Suggested Format for Residue Chemistry Study Reports

Nature of the Residues in Livestock

OPPTS 860.1300

The purpose of this document is to suggest the format for final reports (right column) and to provide instructions for creation of Adobe PDF electronic submission documents (left column). The format is modeled after the NAFTA Data Evaluation Record template that will be used by OPP's and PMRA's scientists when this type of study is reviewed. The format is in outline form. The study report will include text and standard tables (detailed below).

Regarding PDF, both 'bookmarks' and 'links' are referenced. Bookmarks and links are similar in function in that both provide the reader with a way to move efficiently through a document as well as across documents. Bookmarks are a type of link that appear in the navigation pane on the left side of the PDF Reader user screen. Links appear within the body of a document as blue text. They permit the reader to jump to other locations with related information in the same document or other electronic documents.

Residue Chemistry Study Reports – NATURE OF THE RESIDUES IN LIVESTOCK	
Instructions to create PDF	**Document Format**
Create Bookmarks for each item in Document Format column.	• Study Title Page. - Statement of Data Confidentiality. *No confidentiality claims can be made for electronically submitted studies at this time.* • GLP Statement. • QA Statement. • Table of Contents.
Create links in summary to related text and tables in body of study report or appendices.	• Executive Summary. - Summary of Background Information & Experimental Design. - Summary of Results
Create links to related tables.	• Background Information and Experimental Design. - Background Information – See Tables 1 and 2. - Experimental Design – See Tables 3 - 7. - Analytical Methodology. - Results and Discussion – See Tables 8 - 12.

Table Formats

Tables should be imported into the PDF document from their native formats. See OPP's detailed technical specifications for creating PDF for details.

Table 1 – Test Compound Nomenclature.

Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

Table 2 – Physicochemical Properties.

Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapor pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log (K_{ow})		
UV/visible absorption spectrum		

Table 3 – General Test Animal Information.

Species	Breed	Age	Gender	Weight at study initiation (kg)	Health status	Description of housing/holding area

Table 4 – Test Animal Dietary Regime.

Diet	Water	Acclimation period	Predosing

Table 5 – Test Animal Dosing Regime.

Regime (oral, dermal, aquaculture)	Level of administered dose (mg/day)	Food consumption (kg/day)	Vehicle (capsule, feed, bolus, etc.)	Timing/ Duration

Table 6 – Test Material Characteristics.

Chemical structure	[Insert structure]	[Insert structure]
Radiolabel position		
Lot No.		
Purity		
Specific activity (Bq)		
Code		

Table 7 – Sample Collection Information.

Milk/Eggs collected	Amount of milk and no. of eggs produced during normal production	Urine, feces and cage wash collected	Interval from last dose to sacrifice	Tissues harvested and analysed
XXX daily		XXX daily	XXX hours	

Table 8 – Summary of Storage Conditions.

Matrix	Storage Temp. (°C)	Actual Study Duration (days or months)	Limit of Demonstrated Storage Stability (days or months)

Table 9 – Total Radioactive Residues (TRRs) in Milk/Eggs, Tissue and Excreta.

Matrix	Collection Timing	Aa–label		Bb–label	
		% TRR	ppm	% TRR	ppm
Urine					
Feces					
Muscle					
Fat					
Kidney					
Liver					
Milk/Eggs					
Upper GI tract					
Lower GI tract					
Other					
Total recovery					

Table 10 – Distribution of the Parent and the Metabolites in Livestock Matrices when Dosed with ^{14}C-labeled Test Compound X.
[Note: Modify the table, and/or add tables, as needed to accommodate the fractionation scheme, matrices analyzed, radiolabel position, sample timing, and other aspects of the experimental design.]

Metabolite Fraction	Urine (TRR = xx ppm)		Feces (TRR = xx ppm)		Muscle (TRR = xx ppm)		Fat (TRR = xx ppm)		Kidney (TRR = xx ppm)		Liver (TRR = xx ppm)		Milk/Egg (TRR = xx ppm)	
	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm
Surface wash														
[Add a row for each identified compound]														
[Unidentified compound]														
Organosoluble														
[Add row for each identified compound]														
[Unidentified compound]														
Aqueous soluble														
[Add row for each identified compound]														
[Unidentified compound]														
Total extractable (Aqueous + organic)														
Total identified														
Total unidentified														
Total bound residues (PES)														
% Accountability Total (ppm)/TRR (ppm)* 100														

Table 11 – Summary of Characterization and Identification of Radioactive Residues in Livestock Matrices Following Application of Radiolabeled [*chemical*] at [*rate*]. [Note: Modify the table and/or add tables as needed to accommodate the fractionation scheme, matrices analyzed, radiolabel positions, sample timing, and other aspects of the experimental design.]

Compound	Muscle		Fat		Kidney		Liver		Milk/Eggs	
	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm
[Parent]										
[Metabolite 1]										
[Metabolite 2]										
[Metabolite 3]										
[Metabolite 4]										
Total identified										
Total characterized										
Total extractable										
Total bound										

Table 12 – Identification of Compounds from Metabolism Study.

Common name/code	Chemical Name	Chemical Structure